

AMENDMENTS TO THE CLAIMS

1. (original) A pharmaceutical formulation, comprising: (a) an active agent having a first fraction and a second fraction, wherein the first fraction is comprised of a plurality of solid particles; and (b) a pharmaceutically acceptable vehicle comprising at least one compound selected from the group consisting of a hydrophilic surfactant, a lipophilic surfactant, a triglyceride and a solubilizer, wherein the first fraction of the active agent is suspended in the vehicle and the second fraction of the active agent is solubilized in the vehicle, said first fraction representing about 5 wt. % to about 80 wt. % of the active agent and said second fraction representing about 20 wt. % to about 95 wt. % of the active agent.

2. (original) The pharmaceutical formulation of claim 1, further including an additional active agent.

3. (original) The pharmaceutical formulation of claim 2, wherein the additional active agent is (a) suspended in the vehicle, (b) partially solubilized and partially suspended in the vehicle, or (c) fully solubilized in the vehicle.

4. (original) The pharmaceutical formulation of claim 2, wherein the additional active agent is at least partially solubilized in the vehicle.

5. (original) The pharmaceutical formulation of claim 1, wherein the first fraction represents about 5 wt. % to about 80 wt. % of the active agent, and the second fraction represents about 20 wt. % to about 95 wt. % of the active agent.

6. (original) The pharmaceutical formulation of claim 5, wherein the first fraction represents about 30 wt. % to about 80 wt. % of the active agent, and the second fraction represents about 20 wt. % to about 70 wt. % of the active agent.
7. (original) The pharmaceutical formulation of claim 6, wherein the first fraction represents about 50 wt. % to about 70 wt. % of the active agent, and the second fraction represents about 30 wt. % to about 50 wt. % of the active agent.
8. (original) The pharmaceutical formulation of claim 1, wherein the solid particles are comprised of powder, granules, pellets, beads, or combinations thereof.
9. (original) The pharmaceutical formulation of claim 1, wherein the solid particles are associated with each other to form at least one dosage unit comprised of a granule, pellet, bead or tablet suspended in the vehicle.
10. (original) The pharmaceutical formulation of claim 1, wherein the solid particles are contained within at least one capsule suspended in the vehicle.
11. (original) The pharmaceutical formulation of claim 1, wherein the solid particles are prepared by a process selected from melt extrusion, nanoencapsulation, lyophilization, spheronization, coacervation, cryopelletization, crystallization, antisolvent precipitation, precipitation from expanded supercritical fluid, spray drying, spray coating, spray congealing, and combinations thereof.
12. (original) The pharmaceutical formulation of claim 11, wherein the solid particles

are subjected to further processing after preparation thereof.

13. (original) The pharmaceutical formulation of claim 12, wherein the further processing comprises size reduction.

14. (original) The pharmaceutical formulation of claim 13, wherein the size reduction is carried out by a process selected from grinding, milling, micronization, nanosizing, and combination thereof.

15. (original) The pharmaceutical formulation of claim 14, wherein the solid particles have a mean diameter in the range of about 0.1 μm to about 100 μm .

16. (original) The pharmaceutical formulation of claim 13, wherein the size reduction is carried out in the presence of a surfactant, a hydrophilic polymer, a lipid, a gelatin, a saccharide, or a mixture thereof.

17. (original) The pharmaceutical formulation of claim 13, wherein the size reduction is carried out in the presence of the vehicle.

18. (original) The pharmaceutical formulation of claim 12, wherein the further processing comprises treatment with an interfacial modifying agent selected from the group consisting of surfactants, hydrophilic polymers, lipids, gelatins, saccharides, and mixtures thereof.

19. (original) The pharmaceutical formulation of claim 18, wherein the treatment

comprises coating the particles with the interfacial modifying agent.

20. (original) The pharmaceutical formulation of claim 18, wherein the treatment comprises admixture of the particles with the interfacial modifying agent.

21. (original) The pharmaceutical formulation of claim 18, wherein the treatment comprises application of a dry powder of the interfacial modifying agent to the particles.

22. (original) The pharmaceutical formulation of claim 18, wherein the treatment comprises chemical interaction of the particles with the interfacial modifying agent.

23. (original) The pharmaceutical formulation of claim 20, wherein the chemical interaction involves covalent attachment, ionic binding, hydrogen bonding, complexation, adsorption, or a combination thereof.

24. (original) The pharmaceutical formulation of claim 1, wherein the solid particles contain at least one pharmaceutically acceptable excipient.

25. (original) The pharmaceutical formulation of claim 1, further comprising at least one pharmaceutically acceptable additive selected from the group consisting of a stabilizing agent, an antioxidant, a bufferant, an antifoaming agent, a detackifier, a preservative, a chelating agent, a viscomodulator, a tonicifier, a flavorant, a colorant, an odorant, an opacifier, a binder, a filler, a plasticizer, a taste-masking agent, a lubricant, and an enzyme inhibitor.

26. (original) The pharmaceutical formulation of claim 25, wherein said at least one pharmaceutically acceptable additive is a stabilizing agent.

27. (original) The pharmaceutical formulation of claim 26, wherein the stabilizing agent is a suspending agent.

28. (original) The pharmaceutical formulation of claim 27, wherein the suspending agent is selected from the group consisting of microcrystalline cellulose, sodium carboxymethylcellulose, powdered cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, ethylcellulose, ethyl methylcellulose, ethyl hydroxyethylcellulose, attapulgate, bentonite, hectorite, montmorillonite, silica gel, fumed silicon dioxide, colloidal silicon dioxide, acacia, agar, carrageenan, guar gum, locust bean gum, pectin, sodium alginate, propylene glycol alginate, tamarind gum, xanthan gum, carbomers, polyvinyl pyrrolidone, starch, sodium starch glycolate, tragacanth, magnesium aluminum silicate, aluminum silicate, magnesium silicate, gelatin, and glycyrrhizin.

29. (original) The pharmaceutical formulation of claim 1, wherein the solid particles comprise at least one amorphous phase, at least one crystalline phase, or a mixture of at least one amorphous phase and at least one crystalline phase.

30. (original) The pharmaceutical formulation of claim 29, wherein the solid particles further include a stabilizing agent.

31. (original) The pharmaceutical formulation of claim 30, wherein said stabilizing agent is selected from the group consisting of synthetic hydrophilic polymers, surfactants, saccharides, gelatin, and combinations thereof.

32. (original) The pharmaceutical formulation of claim 31, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyalkylene oxides, polyalkylene oxide-substituted C₂-C₆ diols and triols, polyalkylene oxide-substituted saccharides, poly(N-vinyl lactams), and polymers of carboxyvinyl monomers.

33. (original) The pharmaceutical formulation of claim 32, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyethylene glycol, mono-poly(oxyethylene)-substituted propylene glycol, di-(polyoxyethylene)-substituted propylene glycol, mono-poly(oxyethylene)-substituted glycerol, di-(polyoxyethylene)-substituted glycerol, tri-(polyoxyethylene)-substituted glycerol, polyoxyethylated sorbitol, polyoxyethylated glucose, polyvinyl pyrrolidone, poly(N-vinyl caprolactam), and polymers and copolymers of acrylic acid, methacrylic acid and/or esters thereof.

34. (original) The pharmaceutical formulation of claim 31, wherein the saccharides are cellulosic polymers.

35. (original) The pharmaceutical formulation of claim 34, wherein the stabilizing agent is hydroxypropyl methylcellulose.

36. (original) The pharmaceutical formulation of claim 1, wherein the vehicle is

substantially free of water-indispersible wax materials.

37. (original) The pharmaceutical formulation of claim 36, wherein the water-indispersible wax materials are selected from the group consisting of beeswax, paraffin, yellow wax, hydrogenated oils, hydrogenated vegetable oil, hydrogenated soybean oil flakes and mixtures thereof.

38. (original) The pharmaceutical formulation of claim 1, wherein the vehicle is substantially free of added water.

39. (original) The pharmaceutical formulation of claim 1, wherein the vehicle contains less than about 20 wt. % water.

40. (original) The pharmaceutical formulation of claim 1, wherein the vehicle contains less than about 10 wt. % water.

41. (original) The pharmaceutical formulation of claim 1, wherein the vehicle comprises (a) at least one hydrophilic surfactant, (b) at least one lipophilic surfactant, or (c) at least one hydrophilic surfactant and at least one lipophilic surfactant.

42. (original) The pharmaceutical formulation of claim 41, wherein the vehicle comprises at least one hydrophilic surfactant and at least one lipophilic surfactant.

43. (original) The pharmaceutical formulation of claim 1, wherein the vehicle comprises a triglyceride, a solubilizer, or a mixture thereof.

44. (original) The pharmaceutical formulation of claim 1, wherein said at least one compound represents about 1 wt. % to about 99 wt. % of the formulation.

45. (original) The pharmaceutical formulation of claim 44, wherein said at least one compound represents about 10 wt. % to about 90 wt. % of the formulation.

46. (original) The pharmaceutical formulation of claim 45, wherein said at least one compound represents about 20 wt. % to about 80 wt. % of the formulation.

47. (original) The pharmaceutical formulation of claim 1, wherein the active agent is selected from the group consisting of analgesic agents, anesthetic agents, anti-anginal agents, antiarthritic agents, anti-arrhythmic agents, antiasthmatic agents, antibacterial agents, anti-BPH agents, anticancer agents, anticholinergic agents, anticoagulants, anticonvulsants, antidepressants, antidiabetic agents, antidiarrheals, anti-epileptic agents, antifungal agents, antigout agents, antihelminthic agents, antihistamines, antihypertensive agents, antiinflammatory agents, antimalarial agents, antimigraine agents, antimuscarinic agents, antinauseants, antineoplastic agents, anti-obesity agents, antiosteoporosis agents, antiparkinsonism agents, antiprotozoal agents, antipruritics, antipsychotic agents, antipyretics, antispasmodics, antithyroid agents, antitubercular agents, antiulcer agents, anti-urinary incontinence agents, antiviral agents, anxiolytics, appetite suppressants, attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD) drugs, calcium channel blockers, cardiac inotropic agents, beta-blockers, central nervous system stimulants, cognition enhancers, corticosteroids, COX-2 inhibitors, decongestants, diuretics, gastrointestinal

agents, genetic materials, histamine receptor antagonists, hormonolytics, hypnotics, hypoglycemic agents, immunosuppressants, keratolytics, leukotriene inhibitors, lipid-regulating agents, macrolides, mitotic inhibitors, muscle relaxants, narcotic antagonists, neuroleptic agents, nicotine, nutritional oils, parasympatholytic agents, sedatives, sex hormones, sympathomimetic agents, tranquilizers, vasodilators, vitamins, and combinations thereof.

48. (original) The pharmaceutical formulation of claim 47, wherein the active agent is a lipid-regulating agent.

49. (original) The pharmaceutical formulation of claim 48, wherein the lipid-regulating agent is selected from the group consisting of bezafibrate, beclobate, binifibrate, ciplofibrate, clinofibrate, clofibrate, clofibric acid, etofibrate, ezetimibe, etofibrate, fenofibrate, fenofibric acid, gemfibrozil, nicofibrate, pirifibrate, probucol, ronifibrate, simfibrate, and theofibrate.

50. (original) The pharmaceutical formulation of claim 49, wherein the lipid-regulating agent is fenofibrate.

51. (original) The pharmaceutical formulation of claim 47, wherein the active agent is a sex hormone.

52. (original) The pharmaceutical formulation of claim 51, wherein the active agent is selected from the group consisting of progestins, estrogens, and combinations thereof.

53. (original) The pharmaceutical formulation of claim 51, wherein the active agent comprises (a) a progestin selected from the group consisting of acetoxypregnenolone, allylestrenol, anagestone acetate, chlormadinone acetate, cyproterone, cyproterone acetate, desogestrel, dihydrogesterone, dimethisterone, ethisterone (17 α -ethynyltestosterone), ethynodiol diacetate, flurogestone acetate, gestadene, hydroxyprogesterone, hydroxyprogesterone acetate, hydroxyprogesterone caproate, hydroxymethylprogesterone, hydroxymethylprogesterone acetate, 3-ketodesogestrel, levonorgestrel, lynestrenol, medrogestone, medroxyprogesterone acetate, megestrol, megestrol acetate, melengestrol acetate, norethindrone, norethindrone acetate, norethisterone, norethisterone acetate, norethynodrel, norgestimate, norgestrel, norgestrienone, normethisterone, and progesterone; and (b) an estrogen selected from the group consisting of 17 β -estradiol, 17 β -estradiol benzoate, 17 β -estradiol valerate, 17 β -estradiol cypionate, 17 β -estradiol heptanoate, 17 β -estradiol decanoate, 17 β -estradiol acetate, 17 β -estradiol diacetate, ethynylestradiol, ethynylestradiol 3-acetate, ethynylestradiol 3-benzoate, estriol, estriol succinate, polyestrol phosphate, estrone, estrone acetate, estrone sulfate, piperazine estrone sulfate, quinestrol, and mestranol.

54. (original) The pharmaceutical formulation of claim 53, wherein the active agent comprises progesterone and 17 β -estradiol.

55. (original) The pharmaceutical formulation of claim 52, wherein the active agent comprises an estrogen.

56. (original) The pharmaceutical formulation of claim 55, wherein the estrogen is 17 β -estradiol.

57. (original) The pharmaceutical formulation of claim 52, wherein the active agent comprises a progestin.

58. (original) The pharmaceutical formulation of claim 57, wherein the progestin is progesterone.

59. (original) The pharmaceutical formulation of claim 1, wherein either the first fraction of the active agent, the second fraction of the active agent, or both the first and second fractions of the active agent are formulated for immediate release, pulsatile release, controlled release, extended release, delayed release, targeted release, or targeted delayed release of the active agent.

60. (original) The pharmaceutical formulation of claim 59, wherein the first fraction of the agent and the second fraction of the active agent have different release profiles.

61. (original) The pharmaceutical formulation of claim 59, wherein the first fraction of the active agent further comprises a means for controlling release of the active agent from the suspended particles.

62. (original) The pharmaceutical formulation of claim 61, wherein the second fraction of the active agent comprises an immediate release composition.

63. (original) The pharmaceutical formulation of claim 61, wherein the second fraction of the active agent exhibits an immediate release profile.

64. (original) The pharmaceutical formulation of claim 63, wherein the second fraction provides for release of at least 50% of the active agent contained therein within 30 minutes at 37°C. as evaluated using standard USP dissolution test equipment.

65. (original) The pharmaceutical formulation of claim 64, wherein the second fraction provides for release of at least 75% of the active agent contained therein within 30 minutes at 37°C. as evaluated using standard USP dissolution test equipment.

66. (original) The pharmaceutical formulation of claim 65, wherein the second fraction provides for release of at least 90% of the active agent contained therein within 30 minutes at 37°C. as evaluated using standard USP dissolution test equipment.

67. (original) The pharmaceutical formulation of claim 1, further including a means for physically segregating the first and second fractions so as to prevent contact therebetween.

68. (original) The pharmaceutical formulation of claim 67, wherein the means for physically segregating the first and second fractions is comprised of a vehicle-impermeable coating on the solid particles.

69. (original) The pharmaceutical formulation of claim 67, wherein the solid particles of the second fraction are associated with each other to form at least one dosage unit comprised of a granule, pellet, bead or tablet, and the means for physically segregating the first and second fractions is comprised of a vehicle-impermeable coating on said at least one dosage unit.

70. (original) The pharmaceutical formulation of claim 67, wherein the formulation is housed within a dosage form and the means for physically segregating the first and second fractions comprises a wall, a plug, a septum dividing the dosage form into a first region that contains the first fraction and a second region that contains the second fraction.

71. (original) The pharmaceutical formulation of claim 70, wherein the dosage form is a capsule.

72. (original) A dosage form comprising the pharmaceutical formulation of claim 1.

73. (currently amended) The dosage form of claim ~~71~~ 72, comprised of a capsule, preconcentrate, drop, or drink.

74. (original) A pharmaceutical system for administration of an active agent, comprising: (a) an active agent; and (b) a pharmaceutically acceptable vehicle comprising at least one compound selected from the group consisting of a hydrophilic surfactant, a lipophilic surfactant, a triglyceride and a solubilizer, wherein the relative

amounts of the active agent and the vehicle are such that upon admixture thereof, a first fraction of the active agent is suspended in the vehicle, and a second fraction of the active agent is solubilized in the vehicle, wherein the second fraction represents about 20 wt. % to about 95 wt. % of the total active agent in the formulation.

75. (original) The pharmaceutical system of claim 74, wherein the first fraction represents about 10 wt. % to about 80 wt. % of the active agent, and the second fraction represents about 20 wt. % to about 90 wt. % of the active agent.

76. (original) The pharmaceutical system of claim 75, wherein the first fraction represents about 30 wt. % to about 80 wt. % of the active agent, and the second fraction represents about 20 wt. % to about 70 wt. % of the active agent.

77. (original) The pharmaceutical system of claim 76, wherein the first fraction represents about 50 wt. % to about 70 wt. % of the active agent, and the second fraction represents about 30 wt. % to about 50 wt. % of the active agent.

78. (original) The pharmaceutical system of claim 77, wherein the solid particles are comprised of powder, granules, pellets, beads, or combinations thereof.

79. (original) The pharmaceutical system of claim 74, wherein the solid particles are associated with each other to form at least one dosage unit comprised of a granule, pellet, bead or tablet.

80. (original) The pharmaceutical system of claim 79, wherein the solid particles are

contained within a capsule.

81. (original) The pharmaceutical system of claim 79, wherein the solid particles are prepared by a process selected from melt extrusion, nanoencapsulation, lyophilization, spheronization, coacervation, cryopelletization, crystallization, antisolvent precipitation, precipitation from expanded supercritical fluid, spray drying, spray coating, spray congealing, and combinations thereof.

82. (original) The pharmaceutical system of claim 81, wherein the solid particles are subjected to further processing after preparation thereof.

83. (original) The pharmaceutical system of claim 82, wherein the further processing comprises size reduction.

84. (original) The pharmaceutical system of claim 83, wherein the size reduction is carried out by a process selected from grinding, milling, micronization, nanosizing, and combination thereof.

85. (original) The pharmaceutical system of claim 84, wherein the solid particles have a mean diameter in the range of about 0.1 μm to about 100 μm .

86. (original) The pharmaceutical system of claim 83, wherein the size reduction is carried out in the presence of a surfactant, a hydrophilic polymer, a lipid, a gelatin, a saccharide, or a mixture thereof.

87. (original) The pharmaceutical system of claim 83, wherein the size reduction is carried out in the presence of the vehicle.

88. (original) The pharmaceutical system of claim 82, wherein the further processing comprises treatment with an interfacial modifying agent selected from the group consisting of surfactants, hydrophilic polymers, lipids, gelatins, saccharides, and mixtures thereof.

89. (original) The pharmaceutical system of claim 88, wherein the treatment comprises coating the particles with the interfacial modifying agent.

90. (original) The pharmaceutical system of claim 88, wherein the treatment comprises admixture of the particles with the interfacial modifying agent.

91. (original) The pharmaceutical system of claim 88, wherein the treatment comprises application of a dry powder of the interfacial modifying agent to the particles.

92. (original) The pharmaceutical system of claim 88, wherein the treatment comprises chemical interaction of the particles with the interfacial modifying agent.

93. (original) The pharmaceutical system of claim 92, wherein the chemical interaction involves covalent attachment, ionic binding, hydrogen bonding, complexation, adsorption, or a combination thereof.

94. (original) The pharmaceutical system of claim 74, wherein the solid particles contain at least one pharmaceutically acceptable excipient.

95. (original) The pharmaceutical system of claim 74, wherein the vehicle further comprises at least one pharmaceutically acceptable additive selected from the group consisting of a stabilizing agent, an antioxidant, a bufferant, an antifoaming agent, a detackifier, a preservative, a chelating agent, a viscomodulator, a tonicifier, a flavorant, a colorant, an odorant, an opacifier, a binder, a filler, a plasticizer, a taste-masking agent, a lubricant, and an enzyme inhibitor.

96. (original) The pharmaceutical system of claim 95, wherein said at least one pharmaceutically acceptable additive is a stabilizing agent.

97. (original) The pharmaceutical system of claim 96, wherein the stabilizing agent is a suspending agent.

98. (original) The pharmaceutical system of claim 97, wherein the suspending agent is selected from the group consisting of microcrystalline cellulose, sodium carboxymethylcellulose, powdered cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, ethylcellulose, ethyl methylcellulose ethyl hydroxyethylcellulose, attapulgate, bentonite, hectorite, montmorillonite, silica gel, fumed silicon dioxide, colloidal silicon dioxide, acacia, agar, carrageenan, guar gum, locust bean gum, pectin, sodium alginate, propylene glycol alginate, tamarind gum, xanthan gum, carbomers, polyvinyl pyrrolidone, starch, sodium starch glycolate, tragacanth, magnesium aluminum silicate, aluminum silicate, magnesium silicate,

gelatin, and glycyrrhizin.

99. (original) The pharmaceutical system of claim 74, wherein the solid particles comprise at least one amorphous phase, at least one crystalline phase, or a mixture of at least one amorphous phase and at least one crystalline phase.

100. (original) The pharmaceutical system of claim 99, wherein the solid particles further include a stabilizing agent.

101. (original) The pharmaceutical system of claim 100, wherein said stabilizing agent is selected from the group consisting of synthetic hydrophilic polymers, surfactants, saccharides, gelatin, and combinations thereof.

102. (original) The pharmaceutical system of claim 101, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyalkylene oxides, polyalkylene oxide-substituted C₂-C₆ diols and triols, polyalkylene oxide-substituted saccharides, poly(N-vinyl lactams), and polymers of carboxyvinyl monomers.

103. (original) The pharmaceutical system of claim 102, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyethylene glycol, mono-poly(oxyethylene)-substituted propylene glycol, di-(polyoxyethylene)-substituted propylene glycol, mono-poly(oxyethylene)-substituted glycerol, di-(polyoxyethylene)-substituted glycerol, tri-(polyoxyethylene)-substituted glycerol, polyoxyethylated sorbitol, polyoxyethylated glucose, polyvinyl pyrrolidone, poly(N-vinyl caprolactam), and polymers and copolymers of acrylic acid, methacrylic acid

and/or esters thereof.

104. (original) The pharmaceutical system of claim 103, wherein the saccharides are cellulosic polymers.

105. (original) The pharmaceutical system of claim 104, wherein the stabilizing agent is hydroxypropyl methylcellulose.

106. (original) The pharmaceutical system of claim 74, wherein the vehicle is substantially free of water-indispersible wax materials.

107. (original) The pharmaceutical system of claim 106, wherein the water-indispersible wax materials are selected from the group consisting of beeswax, paraffin, yellow wax, hydrogenated oils, hydrogenated vegetable oil, hydrogenated soybean oil flakes and mixtures thereof.

108. (original) The pharmaceutical system of claim 74, wherein the vehicle is substantially free of added water.

109. (currently amended) The pharmaceutical system of claim ~~108~~ 74, wherein the vehicle contains less than about 20 wt. % water.

110. (original) The pharmaceutical system of claim 109, wherein the vehicle contains less than about 10 wt. % water.

111. (currently amended) The pharmaceutical system of claim ~~110~~ 74, wherein the vehicle comprises (a) at least one hydrophilic surfactant, (b) at least one lipophilic surfactant, or (c) at least one hydrophilic surfactant and at least one lipophilic surfactant.

112. (original) The pharmaceutical system of claim 111, wherein the vehicle comprises at least one hydrophilic surfactant and at least one lipophilic surfactant.

113. (original) The pharmaceutical system of claim 74, wherein the vehicle comprises a triglyceride, a solubilizer, or a mixture thereof.

114. (original) The pharmaceutical system of claim 74, wherein the active agent is selected from the group consisting of analgesic agents, anesthetic agents, anti-anginal agents, antiarthritic agents, anti-arrhythmic agents, antiasthmatic agents, antibacterial agents, anti-BPH agents, anticancer agents, anticholinergic agents, anticoagulants, anticonvulsants, antidepressants, antidiabetic agents, antidiarrheals, anti-epileptic agents, antifungal agents, antigout agents, antihelminthic agents, antihistamines, antihypertensive agents, antiinflammatory agents, antimalarial agents, antimigraine agents, antimuscarinic agents, antinauseants, antineoplastic agents, anti-obesity agents, antiosteoporosis agents, antiparkinsonism agents, antiprotozoal agents, antipruritics, antipsychotic agents, antipyretics, antispasmodics, antithyroid agents, antitubercular agents, antiulcer agents, anti-urinary incontinence agents, antiviral agents, anxiolytics, appetite suppressants, attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD) drugs, calcium channel blockers, cardiac inotropic agents, beta-blockers, central nervous system stimulants, cognition

enhancers, corticosteroids, COX-2 inhibitors, decongestants, diuretics, gastrointestinal agents, genetic materials, histamine receptor antagonists, hormonolytics, hypnotics, hypoglycemic agents, immunosuppressants, keratolytics, leukotriene inhibitors, lipid-regulating agents, macrolides, mitotic inhibitors, muscle relaxants, narcotic antagonists, neuroleptic agents, nicotine, nutritional oils, parasympatholytic agents, sedatives, sex hormones, sympathomimetic agents, tranquilizers, vasodilators, vitamins, and combinations thereof.

115. (original) The pharmaceutical system of claim 114, wherein the active agent is a lipid-regulating agent.

116. (original) The pharmaceutical system of claim 115, wherein the lipid-regulating agent is selected from the group consisting of bezafibrate, beclobrate, binifibrate, ciprofibrate, clonofibrate, clofibrate, clofibric acid, etofibrate, ezetimibe, etofibrate, fenofibrate, fenofibric acid, gemfibrozil, nicofibrate, pirifibrate, probucol, ronifibrate, simfibrate, and theofibrate.

117. (original) The pharmaceutical system of claim 116, wherein the lipid-regulating agent is fenofibrate.

118. (original) The pharmaceutical system of claim 114, wherein the active agent is a sex hormone.

119. (original) The pharmaceutical system of claim 118, wherein the active agent is selected from the group consisting of progestins, estrogens, and combinations thereof.

120. (original) The pharmaceutical system of claim 118, wherein the active agent comprises (a) a progestin selected from the group consisting of acetoxypregnenolone, allylestrenol, anagestone acetate, chlormadinone acetate, cyproterone, cyproterone acetate, desogestrel, dihydrogesterone, dimethisterone, ethisterone (17 α -ethynyltestosterone), ethynodiol diacetate, flurogestone acetate, gestadene, hydroxyprogesterone, hydroxyprogesterone acetate, hydroxyprogesterone caproate, hydroxymethylprogesterone, hydroxymethylprogesterone acetate, 3-ketodesogestrel, levonorgestrel, lynestrenol, medrogestone, medroxyprogesterone acetate, megestrol, megestrol acetate, melengestrol acetate, norethindrone, norethindrone acetate, norethisterone, norethisterone acetate, norethynodrel, norgestimate, norgestrel, norgestrienone, normethisterone, and progesterone; and (b) an estrogen selected from the group consisting of 17 β -estradiol, 17 β -estradiol benzoate, 17 β -estradiol valerate, 17 β -estradiol cypionate, 17 β -estradiol heptanoate, 17 β -estradiol decanoate, 17 β -estradiol acetate, 17 β -estradiol diacetate, ethynylestradiol, ethynylestradiol 3-acetate, ethynylestradiol 3-benzoate, estriol, estriol succinate, polyestrol phosphate, estrone, estrone acetate, estrone sulfate, piperazine estrone sulfate, quinestrol, and mestranol.

121. (original) The pharmaceutical system of claim 120, wherein the active agent comprises progesterone and 17 β -estradiol.

122. (original) The pharmaceutical system of claim 119, wherein the active agent comprises an estrogen.

123. (original) The pharmaceutical system of claim 122, wherein the estrogen is 17 β -estradiol.

124. (original) The pharmaceutical system of claim 118, wherein the active agent comprises a progestin.

125. (original) The pharmaceutical system of claim 124, wherein the progestin is progesterone.

126. (original) The pharmaceutical system of claim 74, wherein either the first fraction of the active agent, the second fraction of the active agent, or both the first and second fractions of the active agent are formulated for immediate release, pulsatile release, controlled release, extended release, delayed release, targeted release, or targeted delayed release of the active agent.

127. (original) The pharmaceutical system of claim 126, wherein the first fraction of the agent and the second fraction of the active agent have different release profiles.

128. (original) The pharmaceutical system of claim 126, wherein the first fraction of the active agent further comprises a means for controlling release of the active agent from the suspended particles.

129. (original) The pharmaceutical system of claim 128, wherein the second fraction of the active agent comprises an immediate release composition.

130. (original) The pharmaceutical system of claim 128, wherein the second fraction of the active agent exhibits an immediate release profile .

131. (original) The pharmaceutical system of claim 130, wherein the second fraction provides for release of at least 50% of the active agent contained therein within 30 minutes at 37°C. as evaluated using standard USP dissolution test equipment.

132. (original) The pharmaceutical system of claim 131, wherein the second fraction provides for release of at least 75% of the active agent contained therein within 30 minutes at 37°C. as evaluated using standard USP dissolution test equipment.

133. (original) The pharmaceutical system of claim 132, wherein the second fraction provides for release of at least 90% of the active agent contained therein within 30 minutes at 37°C. as evaluated using standard USP dissolution test equipment.

134. (original) A method of administering an active agent to a mammalian patient, the method comprising orally administering to the patient an amount of the formulation of claim 1 sufficient to deliver a therapeutically effective amount of the active agent to the patient.

135. (original) The method of claim 134, wherein the mammalian patient is human.

136. (original) A method of administering an active agent to a mammalian patient, the method comprising orally administering to the patient a drug delivery system comprised of (a) an active agent; and (b) a pharmaceutically acceptable vehicle

comprising at least one compound selected from the group consisting of a hydrophilic surfactant, a lipophilic surfactant, a triglyceride and a solubilizer, wherein the relative amounts of the active agent and the vehicle are such that upon admixture thereof, a first fraction of the active agent is suspended in the vehicle, and a second fraction of the active agent is solubilized in the vehicle, wherein the second fraction represents about 20 wt. % to about 95 wt. % of the total active agent in the formulation.

137. (original) The method of claim 136, wherein the active agent, the vehicle and the at least one compound are administered simultaneously.

138. (original) The method of claim 137, wherein the active agent, the vehicle and the at least one compound are administered in a single formulation.

139. (original) The method of claim 136, wherein at least two of the active agent, the vehicle and the at least one compound are not administered simultaneously.

140. (original) The method of claim 139, wherein said at least two of the active agent, the vehicle and the at least one compound are housed in different dosage forms.

141. (original) In a method for reducing interpatient variability with respect to absorption and bioavailability of an orally administered pharmaceutical formulation containing an active agent, the improvement comprising administering the active agent in the pharmaceutical formulation of claim 1.

142. (original) A method for reducing the effect of food on absorption and

bioavailability of an active agent orally administered to a patient, comprising administering the active agent to the patient in the pharmaceutical formulation of claim 1.

143. (original) A method for increasing the onset of a therapeutic effect associated with administration of an active agent to a patient, comprising administering the active agent to the patient in the pharmaceutical formulation of claim 1.

144. (original) A method for both increasing the onset of a therapeutic effect associated with administration of an active agent to a patient and reducing the time to apparent elimination, comprising administering the active agent to the patient in the pharmaceutical formulation of any one of claims 12, 13 or 18.

145. (original) A method for both increasing the onset of a therapeutic effect associated with administration of an active agent to a patient and providing for an extended duration of drug release, the therapeutic effect, or both, comprising administering the active agent to the patient in the pharmaceutical formulation of claim 61.